Insert Date

EPA-SAB-12-001

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Office of Research and Development (ORD) Implementation of its Strategic Research Plans: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)

Dear Administrator Jackson:

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB) and the Office of Research and Development (ORD) Board of Scientific Counselors (BOSC). The SAB is a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. The BOSC is also a balanced, expert public advisory group. It provides extramural scientific information and advice to the ORD Assistant Administrator. This report has not been reviewed for approval by the agency, and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or other agencies in the Executive Branch of the Federal government. Mention of trade names of commercial products does not constitute a recommendation for use. Reports of the SAB are posted on the EPA website at http://www.epa.gov/sab, and reports of the BOSC are posted on the EPA website at http://www.epa.gov/osp/bosc.

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Acronyms and Abbreviations

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1. EXECUTIVE SUMMARY

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1.1.1. Heading Level 3

Heading Level 4

2. BACKGROUND AND CHARGE

In 2012, the Office of Research and Development (ORD) developed strategic research action plans for its six research areas and an overview plan after receiving advice from the SAB and BOSC in 2011 [U.S. EPA SAB 2012). The restructured research programs comprise six program areas: Air, Climate, and Energy; Safe and Sustainable Water Resources; Sustainable and Healthy Communities; Chemical Safety for Sustainability; Human Health Risk Assessment; and Homeland Security. ORD requested additional advice in 2012 on ORD's research implementation plans, efforts to strengthen program integration; and efforts to strengthen and measure innovation.

The SAB and the BOSC held a public meeting on July 10-11, 2012, to discuss the strategic research action plans, information about five integration topics presented by ORD (Nitrogen; Global Climate Change; Children's Health/Environmental Justice; Applying new chemical assessment approaches in human health risk assessment; Endocrine-mediated Dose-Response) and ORD efforts to encourage innovation. SAB and BOSC also held a public teleconference on September xx, 2012 to discuss a draft of this report.

ORD requested the SAB and BOSC address: 1) three charge questions related to first year progress, sustainability, and balancing immediate needs and emerging issues for each of the major research areas 2) specific charge questions for each program area; and 3) general questions pertaining to integration and innovation in ORD programs. Appendix A provides ORD's charge to the SAB and BOSC.

Section 3 provides an overview of major findings and recommendations related to the charge questions below.

1. First year progress. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

2. Sustainability. How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

3. Balancing immediate program needs and emerging issues. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

4. Integration. Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

5. How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Section 4 of this report provides more program-specific detail and responses to the specific charge questions for each program area.

3. OVERVIEW OF MAJOR FINDINGS AND RECOMMENDATIONS

3.1. Introduction

3.1.1. Heading Level 3

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3.2. First year progress

3.2.1. Heading Level 3

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

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3.3. Sustainability

3.3.1. Heading Level 3

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

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Heading Level

3.4. Balancing immediate program needs and emerging issues.

3.4.1. Heading Level 3

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

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3.5. Integration

3.5.1. Heading Level 3

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

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3.6. Innovation

3.6.1. Heading Level 3

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Commented [j1]: Reinsert Rosemarie's section on innovation that was in first draft sent by Angela. Somehow it got dropped along the way..

4. PROGRAM-SPECIFIC RESPONSES

4.1. Air, Climate and Energy

4.1.1. Overview questions

First year progress

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4.1.2. Program –specific questions

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Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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4.2. Chemical Safety for Sustainability

4.2.1. Overview questions

First year progress

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Second Program Specific Question Title

Text of Program-specific question

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4.3. Human Health Risk Assessment

These general comments supplement the answers to the charge questions; they address issues that extend beyond the specific charge questions provided by the EPA. They cover interactions among the four themes of the HHRA and of the HHRA across the set of research programs.

The Agency should consider the critical place of risk assessment in the overall activities of EPA and how to best integrate HHRA's thematic tasks to maximize application, problem scoping and management to support all of the research programs in ORD. The vision as currently articulated in the SRAP is: "The Agency will generate timely, credible human health risk assessments to support all priority Agency risk management decisions, thereby enabling the Agency to better predict and prevent risk." Thus, risk assessment represents a methodological foundation for activities of multiple research programs and it should not be placed in a siloed fashion into a single SRAP. Various reports, from the EPA, the National Research Council, and other bodies, have urged improvements to approaches to risk

assessment. The EPA has already made significant steps towards implementing some of those recommended improvements, but a more cohesive approach to risk assessment could be taken across the six research areas. Figure 4, describing the interrelationships among the six programs, do not adequately capture the underpinning and broad translational role of risk assessment within EPA.

The present plan provides a straightforward description of activities within the four themes, but neither provides a strong overall vision nor identifies points for synergism across the four components. At this point, the four themes have certain commonalities and their merger into a single program is reflective of these cross-cutting elements, particularly the reliance on the quantitative methods of risk assessment. In discussions during the meeting of the SAB and BOSC, it was apparent that the HHRA team fully recognized that integration is needed and that synergies can be achieved. These limitations of the current plan are well recognized and there is intent to address them.

The EPA and the staff of the HHRA have substantial expertise in the methods of risk assessment and their application. With an extensive portfolio of risk assessment activities, the HHRA provides a superb platform for carrying out applied research and we urge the leadership of the HHRA to pro-actively utilize this opportunity to advance the risk sciences. An agenda of research should be maintained that builds strategically on this opportunity and attention given to assuring that such methodological research is not set aside.

EPA should carefully examine the placement of the risk sciences within the Agency to assure that there is sufficient integration and connection among risk scientists. Are the risk scientists sufficiently connected? The Risk Forum provides a platform for discussing specific issues, but perhaps a venue is needed for broader discussion and collaboration

4.3.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The ORD research programs appear to be progressing very well in the first year of implementation. However, the SAB and BOSC noted that it is rather early to evaluate the trajectory of progress, and that much remains to be done in the coming years. There is an inherent tension and competition within the program between the need to produce various assessments in a timely fashion and to incorporate strategies based in "new and emerging" science into its activities. ORD should explicitly acknowledge this inherent tension and consider it in setting benchmarks for the program.

The SRAP provides a straightforward description of activities within four themes (Theme 1: Integrated Risk Information System (IRIS) health hazard and dose response assessments; Theme 2: Integrated Science Assessments (ISAs) of criteria air pollutants; Theme 3: Community Risk and Technical Support for exposure and health assessments; and Theme 4: Modernizing Risk Assessment Methods). The research activities planned for FY 13 and future years seem appropriate for answering the science

questions in the Strategic Research Action Plan. There are potential challenges that may interfere with the planned agenda over the longer-term. One is the already mentioned trade-off between the demands of producing timely assessment while assuring that methodological research continues. In addition, resource limitations and recent unfunded mandates placed on ORD may constrain efforts to carry out this ambitious set of research activities. Decisions about what to prioritize and what to omit will be challenging, and should be made only after the overall vision has been further developed.

Considering the linkage between the HHRA program and decision making, it is important not to overlook the importance of the exposure sciences, which are not sufficiently reflected in the SRAP. The upcoming report from the National Research Council on the exposure sciences is likely to increase attention to this area and provide prioritized research needs. The discussion of exposure sciences should be expanded beyond the brief discussion in Theme 3 (Community Risk and Technical Support) in the plan. All HHRA assessments will benefit substantially from state-of-the-art exposure data and methods. The HHRA program will also benefit from enhanced ties to the ecological risk assessment community.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The HHRA SRAP did not contain any specific mention of sustainability, yet this apparent omission does not reflect omission of sustainability from the program's actual mission. The contributions made by the HHRA program in advancing the science underlying the NAAQS have driven major air quality improvements nationwide that further sustainability goals. Similarly, the role of the HHRA program in producing high-quality risk assessments (in the IRIS program) and rapid risk assessments (PPRTVs) contributes to the goal of identifying and controlling health risks from toxic chemicals and developing new tools to predict chemical risk and to further green chemistry. Finally, efforts to develop and improve the ability to identify and measure cumulative risks can help advance environmental justice and community sustainability.

The SAB and BOSC recommend that the HHRA program more clearly and explicitly communicate its significant contributions to sustainability. Furthermore, the HHRA program's efforts to train risk assessors in state-of-the-art methods and approaches through the Risk Assessment Training and Experience (RATE) program, which provides comprehensive risk assessment guidance and training, will ensure future contributions to sustainability.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

EPA will need to think and act creatively to deal with the likelihood of reduced budgets, while at the same time addressing requests for assistance from various programs and from an increasingly informed

public. In addition, the release of the three groundbreaking National Research Council reports (Tox 21, Science & Decisions, and Phthalates & Cumulative Risk) provides an agenda and an impetus for EPA to transform its overall approach to risk assessment. This transformation needs to occur in parallel with the ongoing production of individual risk assessments, since there is a continuing need to provide the most credible possible risk numbers for decision makers. ORD needs to build capacity to incorporate the new toxicology data into a new risk assessment approach.

In addition to more careful coordination and priority setting with the CSS program, EPA has several other options for leveraging available resources. For example, EPA might consider the development of cooperative agreements with outside parties via the Federal Technology Transfer Act (FTTA). This act specifically allows for external funding to be put into the agency in the pursuit of technology developed by EPA, such as that developed on emerging issues and/or issues related to sustainability. EPA might also link more directly with other federal agencies, such as the Agency for Toxic Substances and Disease Registry (ATSDR), which has a similar mission for hazard identification and dose-response assessment. For example, EPA might consider jointly developing PPRVTs and Minimal Risk Levels with ATSDR. Moreover, if EPA has found its current collaboration around toxicity assessment with California to be helpful, EPA could partner with other outside parties, such as the State of Minnesota, NSF International, or even other governments that also conduct similar hazard identification and dose-response assessment work. Of course, NCEA would be well served to work even more closely with existing groups within the Agency, such as EPA's Office of Water or its Office of Pesticides Program for developing dose-response assessment values. For example, adding recent Office of Pesticides Program risk assessment values, or updating older pesticide values, would be a valuable addition/update to IRIS.

EPA could also respond to this likelihood of reduced budgets by addressing emerging problems through the use of newer tools, such as high throughput assays, that have the promise of high-quality and abundant data at reasonable cost. These approaches such as high throughput assays should be assessed and pursued for use by HHRA in order to improve, streamline and make more cost effective the present assessment programs Demonstration of these emerging tools and early feedback would serve to improve their utility, efficacy, and acceptance. Another advantage in the use of these emerging tools is that they have the potential to expedite the overall assessment.

In addition, EPA might consider active partnerships with other entities in order to build opportunities to use high throughput testing and new observational epidemiology studies based in established cohorts. There are several advantages of this approach including the reduced use of experimental animals, the direct use of human studies, and the ready application of high throughput testing.

Furthermore, EPA should consider producing screening risk levels for chemicals, similar to the established Thresholds of Toxicology Concern (TTC) or the developing concept of Conditional Toxicity Value (CTP). The TTC approach is well established for food contaminants and is being actively studied for applicability to other environmental media. The CTP is more innovative in that it incorporates consideration of new toxicity testing methods. Both approaches would support the establishment of interim risk values for many chemicals of concern. These values could then be used to guide risk management until additional chemical-specific data become available. If EPA decides to take this

approach, then linkages with other agencies or organizations with interest in these methods will be particularly helpful.

EPA should consider incorporating shorter-term testing to improve the basis of its risk assessments, as long as time lines for the risk assessment are not unduly lengthy, and the delay is not associated with remediable, ongoing human exposures and potentially significant human health or ecological risk. EPA's NCEA should also consider how to prioritize within themes 3 and 4 of its HHRT given the possibility of limited resources.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Much of the work of HHRA focuses upon mandated activity and is highly task-oriented. Because of the large amount of mandated work and because HHRA outputs (e.g. IRIS) provide the hazard identification and dose-response assessment basis, in part, for the regulatory and advisory work of EPA, integration efforts should be prioritized carefully so as not to impose unnecessary burdens (undue time and effort) that could detract from core activities.

Nevertheless there were a number of research topics identified for which there is high need or potential for integration/collaboration between HHRA and the other programs. SAB and BOSC recommend that cross-program collaboration between CSS and HHRA be emphasized more strongly in the SRAPs for the two programs. While cross- program integration is proposed, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and priority setting is not clear. Even within HHRA, there is not adequate connection and synergy. For example, transparent evidence synthesis is integral to both the IRIS Program and the development of the ISAs, but this connection is not made. The SAB and BOSC recommend that ORD revise the CSS and HHRA documents so that they more clearly communicate the inter-related science and research priorities for these two programs.

The areas of children's health and of the health and exposures of other sensitive and vulnerable subgroups require a high level of integration across all ORD research programs. The HHRA strategic research action plan should identify key gaps between research outputs and assessment needs so that ORD can focus research to address the needed integrative models including exposure assessment, computational toxicity, developmental toxicity, in vivo effects, animal data, mechanistic models and pathway analysis. The HHRA activities can provide multiple reference doses specifically, including short-term duration doses suitable for evaluating windows of vulnerability to high exposure. HHRA assessments should also identify populations that may face greater risks due to genetic or other factors and quantify these risks, using the new possibilities afforded by advances in genetics and exposure assessment. There is need for integration of HHRA into various rapid risk assessment processes (e.g., in conjunction with Homeland Security), when there are needs for assessment of chemo-toxicity of short-term exposures and for the development of Provisional Advisory Levels (PALs). HHRA would also

benefit from interaction with EPA's Office of Toxic Substances, and specifically in its development of Acute Exposure Guideline Levels (AEGLs).

ORD should monitor for topics that are candidates for integrated efforts and ORD should have approaches in place for initiating integrative activities and giving them appropriate priority. Very importantly, when new issues requiring integration arise within HHRA all programs should be notified, since there may be interests in the same topics from researchers in other ORD research program. Additionally, HHRA, as for other programs, would benefit from the integration of social, behavioral, and decision scientists into the activities related to risk assessment methodology in support of decision-making. This recommendation from the prior review remains relevant.

Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Beyond the findings and recommendations provided in section 3.5 above, there are opportunities for innovation to help "reinvent" the IRIS program by doing the following: 1) substantially shortening and streamlining the documents to make them easier to use and to review; 2) incorporating Tox21 data, initially in qualitative discussions, then in parallel with traditional toxicology data, and ultimately, as appropriate, as part of critical pathway-based extrapolations; and 3) incorporating the key recent recommendations from the National Research Council Science and Decisions report on reforming risk assessment, with a particular focus on grappling with cumulative risk, making implicit default assumptions more explicit, improving characterization of uncertainty, and not assuming that the dose-response for all non-carcinogens includes a threshold. These points are all reflected in the HHRA SRAP, but not as clearly as they could be.

4.3.2. Program –specific questions

Modernizing methods

What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)? Additionally, what approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?

The SAB and BOSC recommend that ORD begin, as soon as possible, to implement and integrate new types of data and methods into risk assessments. New methods may be used in qualitative if not quantitative ways in such ORD products as PPTRVs (Provisional Peer Reviewed Toxicity Values derived by EPA's Superfund programs) and IRIS reviews. The HHRA program has begun to consider "omics" data (e.g., genomics, proteomics, and metabolomics) and innovations described in the *Science and Decisions* report in IRIS and other risk assessments. ORD should continue to integrate this

information as quickly and effectively as possible as one way to ensure that risk assessors and risk managers become familiar with new types of data and methods and recognize the utility of the new information. For example, each upcoming IRIS assessment for which the chemical has undergone testing under the Tox21 regime should at least present the data and incorporate it into a qualitative discussion.

In regard to the variability and uncertainty that may be associated with these new methods, the SAB and BOSC recommends that HHRA incorporate new data and new approaches as they become available and characterize the uncertainty and variability associated with each research result in a transparent manner. As more data become available and methods are tested further, a component of this work should include comparing traditional and non- traditional approaches to evaluate the outcome of using new methods. The data and methods might be helpful in analyzing uncertainty as well.

New methods or approaches are considered widely acceptable when well respected and influential risk assessment programs, including those outside of ORD and those in other agencies, incorporate new approaches in a consistent manner. New approaches and new data will gain greater acceptance by risk assessors and managers if ORD works with multiple EPA programs and other agencies to gain consensus on the use of data and methods. Consensus on each risk assessment is not needed [e.g., the Minimum Risk Levels (MRLs) produced by ATSDR need not match the IRIS reference doses (RfDs) produced by EPA], but consensus should be achieved on recommended methods, approaches, and to the extent possible, application (e.g., BMDL methodology is now widely accepted, although different groups may calculate a different value). Agreement within the risk assessment community on the utility of the new approaches will enhance their credibility with risk managers.

EPA should provide training and education tailored to the information needs and backgrounds of the agency risk managers as well as those outside the agency (risk assessors, risk managers, academia, and science advisors to the communities affected by risk management decisions). The HHRA program has already given this problem careful consideration by meeting with agency risk managers in a focus group venue to learn how risk managers 'receive' information about risk assessments. ORD has also described the Risk Assessment Training and Experience (RATE) program and an outcome for training (FY15). ORD staff already influence peer scientists through offering, planning, and participating in symposia, workshops, and continuing education offerings at professional meetings. ORD is also hosting webinars and other remote learning opportunities. Many of these current activities are aimed not only at NCEA scientists, but also peer scientists.

While these ORD efforts are laudable, education efforts targeted to risk assessors and managers should be offered frequently and should focus on the new tools and methods in order to ensure that the understanding and acceptance by potential users evolves along with the work that is produced. An added advantage is that early training will provide ORD with timely feedback from stakeholders who may be struggling to implement new approaches. Suggestions for training include:

- Sustaining the development of risk assessment methods and their implementation into practice.

- Targeting innovators and influencers in various sectors (e.g., regional offices, state risk assessment programs, academia, science advisors from the non-profit sector, community leaders) for specific training;
- Optimizing training to match the background, experiences, and needs of change leaders;
- Developing coursework and ensuring it is taught in influential toxicology and exposure science academic training programs;
- Developing public health policy training through public health institutes;
- In-laboratory rotations targeting toxicologists and risk assessors unfamiliar with new technologies; and
- Sharing information about the RATE program (course content and focus, audience, and delivery) and implement it as early as possible.

Education and training are resource intensive activities that require dedicated staffing and the support of management, and HHRA should be adding annual output goals in this area.

In regard to the second part of this charge question, which pertains to risk managers' understanding, acceptance and use of these new methods, the SAB and BOSC recommend that the HHRA program systematically study, perhaps through the use of decision science, the utility of the new data sources for decision-making, and determine how evidence from new areas of investigation should be combined or presented along-side of more traditional methods of risk assessment. The SAB and BOSC recommend four key steps to enhance risk manager's understanding, use, and acceptance of the new data and methods that are being developed for implementation by HHRA (data such as high-throughput studies and methods such as recommendations from the National Research Council report *Science and Decisions*). The key steps include: (1) consistent adoption of new approaches across programs; (2) training and education; (3) immediate implementation of new methods, and (4) evaluating the incorporation of new methods into decision-making. It is clear that risk managers need to have information presented in ways that demarcate what is known from what is not known. Risk managers need information that characterizes uncertainty in a useful way. The EPA should conduct research on how to combine results from the new lines of investigation with health risk data from "traditional" toxicity testing and epidemiology. The research should demonstrate the utility of these new data sources for decision-making, not only what risk managers understand about these approaches and how they may use them. ORD should consider involving decision-scientists to study the perceived utility and acceptance of findings by risk managers.

Peer review

How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

The SAB and BOSC reflected on the difficult balance between the essential role of peer review and the need for timeliness in producing risk assessments of public health importance. In some cases, repeated

rounds of demand for peer review may be driven more by external factors rather than by actual limitations of the documents. In other cases, increasingly cumbersome, lengthy, and confusing EPA assessments have made the task of peer review more difficult than it needed to be, and have resulted in negative feedback to the Agency. The SAB and BOSC applaud the commitments in the HHRA action plan to produce more readable, shorter and well-organized IRIS assessments, and this shift should make the peer review process somewhat easier and more efficient in the future. Overall, the SAB and BOSC strongly support HHRA's commitment to the scientific integrity and quality of its HHRA risk assessments and acknowledge that EPA has improved its responsiveness to peer review comments.

In recent risk assessments, EPA staff has stated its implementation of every suggestion made by peer reviewers. The SAB and BOSC recognize that difficult decisions sometimes arise, such as when a peer review recommends use of a different model or a new uncertainty analysis requiring extensive time and resources to produce and that would be unlikely to significantly change or improve the final assessment, or when there is a lack of consensus among peer reviewers. In such cases, the lack of a 'referee' for the peer review process places the Agency in a difficult situation. The SAB and BOSC recommend that EPA consider creating a new role for an independent scientist to review the peer review comments and determine which should be given priority and when they have been adequately addressed. This type of role currently exists for peer review of reports of the National Academy of Sciences as well as for all scientific journals. In other words, there should be a transparent approach to triaging comments received in peer review and giving them priority so as to assure that the most critical revisions are made as efficiently as possible.

The level of peer review should be generally commensurate with the complexity and importance of the document, and with the time-urgency of the assessment, which is the current practice of the HHRA. For example, PPRTV-type assessments appropriately undergo a lesser level of peer review than IRIS assessments, and the degree of review accorded an IRIS assessment varies according to its importance. However, in a few cases, additional mandated reviews have created a highly significant strain on the budget and unusual delays; there is concern about how recent mandates may impair the ability of the HHRA program to achieve its goals and objectives in the coming fiscal year. Budget cuts should not impair efforts to incorporate the new scientific data and methods, as these new methods have the potential to ultimately help improve efficiency and better protect public health by allowing screening-level assessments on many more chemicals than can be addressed today.

The agency should have the overall goal of providing its assessments in a timely way. This goal has not always been met, particularly for the IRIS assessments and the past Criteria Documents. More recently, the Agency has been completing the peer review of the ISAs in a timely fashion, in part because of court-ordered deadlines. Additionally, the switch from the Criteria Document to the ISA format has led to more synthetic and transparent documents that can be more readily reviewed.
Toxicology reviews, reference doses, and cancer slope factors are extremely important in programs across EPA and in environmental and public health actions carried out across the country. It is possible that the reforms already being implemented in the IRIS program, and that lead to greater transparency and stakeholder involvement early in the review process, will result in less onerous peer reviews. EPA will be able to address more concerns more directly during the review and stakeholders can target their comments more effectively in a peer review.

4.3.3. Major recommendations for the HHRA program

- The EPA should broadly examine the placement of risk assessment activities within the Agency and seek to establish connections and integration that will foster ongoing enhancement of methodology.
- The HHRA leadership needs to elaborate a strategic vision that enhances linkages among the thematic areas of the HHRA and with the other research programs and that emphasizes the way that the HHRA program contributes to sustainability.
- A widely reaching plan is needed for incorporating data from emerging technologies, e.g., "omics" and high throughput testing, into EPA risk assessment approaches and for evaluating the utility of these new types of data for decision-making.
- While progress by HHRA has been on pace during its first year, the agenda needs to be set for the longer-term with priorities given to the most critical topics for decision-making, particularly as resources may decline.
- Exposure sciences need greater emphasis within the activities of the HHRA.
- Integration of HHRA approaches with those of other EPA groups would lead to greater efficiency and harmonization of approaches.
- The addition of further social, behavioral, and decision scientists to HHRA would benefit many of its activities and enhance integration.
- Sustained efforts are needed to assure that scientists with HHRA and elsewhere in EPA and decision-makers are fully versed in the latest risk assessment approaches and the interpretation and application of their findings.
- EPA risk managers should also be educated in the new data and approaches in risk assessment, so they feel more confident in the future basing decisions on these approaches.
- Peer reviews of HHRA products could be made more efficient. The plans for changes in the IRIS assessments should benefit peer review. Additionally, the intensity of peer review should reflect the complexity and importance of the product. For extensive peer reviews, it is important to evaluate and improve the process to triage comments so that effort is directed at the points of criticism that are most important and that have significant implications for overall risk estimates and decision-making. A transparent process would be helpful for this purpose, potentially involving an independent referee.

4.4. <u>Safe and Sustainable Water Resources</u>

4.4.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

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Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

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Heading Level

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

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Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

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Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

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4.4.2. Program –specific questions

First program specific question title

Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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4.5. Homeland Security

4.5.1. Heading Level 3

4.5.2. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

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Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

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Heading Level

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

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4.5.3. Program –specific questions

First program specific question title

Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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4.6. Sustainable and Healthy Communitites

4.6.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

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Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

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Heading Level

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4.6.2. Program –specific questions

First program specific question title

Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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REFERENCES

(Use "Un-Numbered Header" Style)

Reference, A. Year. Title of article in all its long, gory detail that runs on and on across multiple lines of text. *Journal* v:p-p.

APPENDIX A: ORD Charge to the SAB and BOSC